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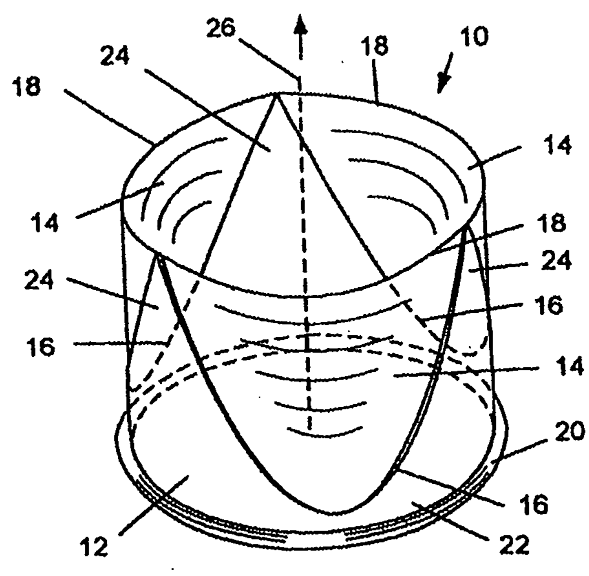
(54) Title: ALTERING HEART VALVE LEAFLET ATTACHMENT GEOMETRY TO INFLUENCE THE LOCATION AND MAGNITUDE OF MAXIMUM LOADED STRESS ON THE LEAFLET

(57) Abstract

The durability of tri–leaflet valves is improved by moving the point of maximum loaded stress on the free edge (18) of the leaflet (14) away from the location of stress risers. The point of maximum loaded stress is moved by changing the geometry of the attachment curve (16) between the leaflet (14) and the valve body (12). The geometry of the attachment curve (16) is changed by changing the shape of the valve body (12) or the shape of the leaflet (14).



Description

Altering Heart Valve Leaflet Attachment Geometry to Influence the Location and Magnitude of Maximum Loaded Stress on the Leaflet

Background Art

The present invention pertains to valves and in particular to tri-leaflet heart valve prostheses.

Ever since 1950, when blood oxygenators made open heart surgery feasible, it has been possible to treat some forms of heart disease by replacing one of the patient s heart valves with a prosthetic valve. Early heart valve prostheses included ball-and-cage valves and disc-and-cage valves in which a ball or a disc was housed in a cage. One side of the cage provided an orifice through which blood flowed either into or out of the heart, depending on the valve being replaced. When blood flowed in a forward direction, the energy of the blood flow forced the ball or disc to the back of the cage allowing blood to flow through the valve. When blood attempted to flow in a reverse direction, or regurgitate , the energy of the blood flow forced the ball or disc into the orifice in the valve and blocked the flow of blood.

A bi-leaflet valve comprised an annular valve body in which two opposed leaflet occluders were pivotally mounted. The occluders were typically substantially rigid, although some designs incorporated flexible leaflets, and moved between a closed position, in which the two leaflets were mated and blocked blood flow in the reverse direction, and an open position, in which the occluders were pivoted away from each other and did not block blood flow in the forward direction. The energy of blood flow caused the occluders to move between their open and closed positions.

A tri-leaflet valve comprised an annular valve body in which three flexible leaflets were mounted to a portion of the valve body, called a stent, located at the circumference of the annulus. Some tri-leaflet valves used rigid leaflets. When blood flowed in the forward direction, the energy of the blood flow deflected the three leaflets away from the center of the annulus and allowed blood to flow through. When blood flowed in the reverse direction, the three leaflets engaged each other in a coaptive region, occluded the valve body annulus and prevented the flow of blood. The valve leaflets were made from tissue, such as specially treated porcine or bovine pericardial tissue, or. more recently, from a man-made material such as polyurethane or another biocompatible polymer.

One of the issues considered in the design of heart valves incorporating flexible leaflets is

the durability of the leaflets. When the valve is in a closed loaded position, that is, when it is closed and under a reverse pressure load, the leaflets experience a loaded stress and the portions of the leaflets near the attachment curve and in engagement with other leaflets, called the commissure, experience high mechanical stress. The commissure is also the location of several physical characteristics, called stress risers, which increase the amount of stress on the leaflet. For example, the commissure is at the edge of the leaflet that is cut by a knife blade. The trauma of being cut by a blade creates stress risers along that edge. Further, the commissure is in the area of the flexible leaflet s coupling to the less flexible valve body, which creates stress risers. Finally, the commissure has small radius corners that create stress risers.

Prior heart valve designs have incorporated flexible stents into the valve body to reduce the mechanical stress at the commissure. Another prior art approach to reducing mechanical stress is to incorporate non-isotropic materials, such as fabric, into the leaflets.

Disclosure of Invention

The invention increases the durability of a valve leaflet coupled to a valve body by moving the leaflet s point of maximum loaded stress away from the location of stress risers.

In general, in one aspect, the invention features a valve comprising a base having a longitudinal axis; a leaflet support coupled to the base; at least a portion of the leaflet support having a non-cylindrical shape relative to the base s longitudinal axis.

Implementations of the invention may include one or more of the following. The valve may further comprise a leaflet coupled to the leaflet support; the shape of the leaflet support being configured to locate a point of maximum loaded stress on the leaflet away from a location of stress risers on the leaflet.

In general, in another aspect, the invention features a valve comprising a valve body and a leaflet coupled to the valve body along an attachment curve. The leaflet has a surface and a free edge. The free edge has a center point. The attachment curve has a first end and a second end. The attachment curve is configured so that a shortest distance measured along the surface of the leaflet between the center of the free edge and the attachment curve is smaller than the distances measured along the surface of the leaflet between the center of the free edge and both the first end and the second end of the attachment curve.

Implementations of the invention may include the following. The coupling between the valve body and the leaflet may be an integral attachment.

In general, in another aspect, the invention features a valve comprising a valve body and a first leaflet coupled to the valve body along an attachment curve. The attachment curve is configured to locate a point of maximum loaded stress on the first leaflet away from a location of stress risers on the first leaflet.

Implementations of the invention may include the following. The valve may comprise a second leaflet and a commissure between the first leaflet and the second leaflet wherein the location of stress risers is the commissure.

In general, in another aspect, the invention features a valve comprising a valve body and a leaflet coupled to the valve body along an attachment curve. The attachment curve is configured to have a region of substantially uniform maximum loaded stress along the attachment curve.

Implementations of the invention may include the following. The leaflet may comprise a surface and a free edge, the free edge comprising a center point. The region of maximum loaded stress may comprise a range of points along the attachment curve being substantially a same distance, measured along the surface of the leaflet, from the center point of the leaflet s free edge. The region of maximum loaded stress may be closer, measured along the surface of the leaflet, than any point along the attachment curve that is not among the points in the region of maximum loaded stress.

In general, in another aspect, the invention features a method of making a valve. A valve body having a longitudinal axis is formed. A leaflet support is coupled to the valve body. An attachment curve for a leaflet on the leaflet support is located such that the point of maximum loaded stress on the leaflet is away from a location of stress risers. The radius of the attachment curve is expanded relative to the longitudinal axis. Location and expansion of the attachment curve are performed iteratively. The leaflet is coupled to the leaflet support at the attachment curve.

In general, in another aspect, the invention features a method of making a valve comprising forming a valve body having a leaflet support having one or more recesses. A leaflet is coupled to one of the recesses of the leaflet support along an attachment curve that has a first end and a second end. The shortest distance along a surface of the leaflet from a center of a free edge of the leaflet to a point along the attachment curve is less than the distance along the surface of the leaflet from the center of the free edge of the leaflet to the first end of the attachment curve.

In general, in another aspect, the invention features a valve comprising a valve body and a leaflet coupled to the valve body along an attachment curve. The attachment curve comprises a first end and a second end. The leaflet is movable between an open position and a closed loaded

position. The leaflet has a point of maximum displacement between the open and closed loaded positions. The shortest distance along a surface of the leaflet from the point of maximum displacement to a point along the attachment curve is less than the distance along the surface of the leaflet from the point of maximum displacement to an end of the attachment curve.

Implementations of the invention may include the following. The point of maximum displacement may be a center of a free edge of the leaflet.

In general, in another aspect, the invention features a valve comprising a valve body that has a base and a leaflet support. The leaflet support has three recesses. A first leaflet is coupled to a first recess of the leaflet support along a first attachment curve. A second leaflet is coupled to a second recess of the leaflet support along a second attachment curve. A third leaflet is coupled to a third recess of the leaflet support along a third attachment curve. Each leaflet engages the other two leaflets to form a first commissure between the first and second leaflets; a second commissure between the second and third leaflets; and a third commissure between the third and first leaflets. The three leaflets form a triple point. The first attachment curve is configured so that the shortest distance along the surface of the first leaflet from the triple point to the first attachment curve is less than the distance along the surface of the first leaflet from the triple point to the first commissure and the distance along the surface of the first leaflet from the triple point to the third commissure. The second attachment curve is configured so that the shortest distance along the surface of the second leaflet from the triple point to the second attachment curve is less than the distance along the surface of the second leaflet from the triple point to the first commissure and the distance along the surface of the second leaflet from the second commissure to the triple point. The third attachment curve is configured so that the shortest distance along the surface of the third leaflet from the triple point to the third attachment curve is less than the distance along the surface of the third leaflet from the triple point to the second commissure and the distance along the surface of the third leaflet from the triple point to the third commissure.

Brief Description of the Drawings

Fig. 1 is a perspective view of a tri-leaflet valve in the open position.

Fig. 2 is a plan view of the valve of Fig. 1.

Fig. 3 is a perspective view of a tri-leaflet valve in the closed loaded position.

Fig. 4 is a plan view of the valve of Fig. 3.

Fig. 5 is a cross-sectional view along lines V on Fig. 4.

Fig. 6 is a view along lines VI on Fig. 3.

Fig. 7 is a plan view of a leaflet.

Fig. 8 is an elevation view of a leaflet, viewed along lines IX on Fig. 7.

Fig. 9 is a graph of normalized distance to the triple point vs. position on the attachment curve.

Fig. 10 is a graph of normalized stress vs. edge position.

Fig. 11 is a perspective view of a leaflet having regions of maximum loaded stress.

Fig. 12 is a perspective view of a portion of a valve with two superimposed leaflets.

Figs. 13 and 14 are perspective views of a portion of a valve with one of the leaflets from Fig. 12.

Fig. 15 is a perspective view of a portion of a valve with three superimposed leaflets.

Figs. 16, 17 and 18 are perspective views of a portion of a valve with one of the leaflets from Fig. 15.

Fig. 19 is an elevation view of a portion of a valve along lines XVIII of Fig. 15, showing three superimposed leaflets.

Fig. 20 is a perspective view of a portion of a valve.

Best Mode for Carrying Out the Invention

A tri-leaflet heart valve prosthesis 10 comprises an annular valve body 12 and three flexible leaflets 14 made of a biocompatible polymer such as silicone or polyurethane, as shown in Fig. 1. Each leaflet is coupled to the valve body along an attachment curve 16. Each leaflet has a free edge 18 that is not coupled to the valve body. A sewing ring 20 is coupled to the base of the valve body 12 and provides a place for sutures to be applied when the valve is implanted. The valve body comprises an annular base 22 and a leaflet support, comprising three shaped posts 24, that supports the leaflets 14.

When fluid flow is in the forward direction, i.e. in the direction of the arrow shown in Fig. 1, the pressure of the blood flow causes the leaflets 14 to deflect away from a central longitudinal axis 26 of the valve body that is generally parallel to the three posts 24. In this open position, the leaflets 14 define a large flow orifice, as shown in Fig. 2. With the leaflets in the open position shown in Figs. 1 and 2, the valve presents little resistance to fluid flow.

When fluid flow is in the reverse direction, i.e. in the direction of the arrow shown in Fig. 3, the pressure of the blood flow causes the leaflets to deflect toward axis 26, as shown in Figs. 3 and 4. In this closed loaded position, where the three leaflets are closed and subject to a load in the reverse direction, each leaflet would occlude more than one-third of the valve body s orifice

were it not for the presence of the other leaflets. Consequently, when the three leaflets deflect toward axis 26, they engage each other and form coaptive areas 28, as shown in Fig. 5, which help the valve seal against reverse flow. Further, when the leaflets press together, each leaflet forms a triple point 30 at the point where the three leaflets come together, as shown in Fig. 6.

The place where the leaflets 14 come together adjacent the posts 24 is called the commissure 32, as shown in Fig. 3. Each leaflet has a small bending radius in the vicinity of the commissure. Further, the flexible leaflet 14 connects to the relatively stiff post 24 in the vicinity of the commissure, as illustrated in Fig. 3. Further, leaflets are generally manufactured by molding and then cutting the leaflet along the free edge, which includes the commissure, to match design criteria. Each of these factors is a stress riser, which makes the commissure 32 a location of high stress risers.

A point at or near a leaflet s triple point 30 experiences the maximum displacement of any point on the leaflet between the valve s open and closed loaded position. If the leaflet is imagined as a collection of non-interconnecting spans connecting the triple point to the attachment curve, the triple-point end of each of those spans experiences the same displacement between the valve s open and closed loaded positions. Therefore, the maximum stress when the leaflet is in its closed loaded position, or maximum loaded stress , will occur along the span with the shortest original length.

In some prior art designs, the span with the shortest original length connects the triple point 30 to the commissure 32, which means the point of maximum loaded stress will occur along this span. As discussed above, the commissure 32 is a location of high stress risers. This coincidence of maximum loaded stress with high stress risers at the commissure 32 produces a high likelihood that the leaflet will fail at the commissure 32.

The invention reduces the likelihood of leaflet failure by moving the location of maximum loaded stress away from the location of stress risers. In particular, the invention reduces the likelihood of leaflet failure by moving the location of maximum loaded stress away from the commissure 32. This is accomplished by changing the geometry of the attachment curve 16 so that the shortest distance along the surface of the leaflet from the triple point 30 to the attachment curve 16 is not along the leaflet s free edge 18. This moves the location of the point of maximum loaded stress away from the free edge 18 and away from the commissure 32.

The location of the point of maximum loaded stress is moved by changing the geometry of the attachment curve. The geometry of the attachment curve is defined by the intersection of the geometry of the leaflet 14 and the geometry of the valve body 12. The geometry of the

attachment curve 16 between a valve body 12 and a leaflet 14 may be changed by altering the leaflet geometry or the valve body geometry in the vicinity of their intersection.

For example, if the leaflet shape is held constant, the attachment curve is different for a cylindrical valve body than it is for a valve body that is either convex or concave relative to cylindrical, as illustrated in Figs. 7 and 8. Leaflet 14 is symmetrical around midline 34. If the valve body has a cylindrical shape where it intersects the leaflet, the attachment curve will have the shape of curve 36. If the valve body has a shape that is concave relative to a cylindrical shape, the attachment curve will have the shape of curve 38, for example. If the valve body has a shape that is convex relative to a cylindrical shape, the attachment curve will have the shape of curve 40, for example.

The distance from the triple point to the attachment curve 38 is different than the distance from the triple point to attachment curve 40, as illustrated in Fig. 9. In Fig. 9, the vertical axis is the normalized distance from the triple point to the attachment curve, with the normalization factor being the distance from the triple point to the commissure. The horizontal axis represents edge position, measured as a percentage of the arc from the commissure to the intersection of the leaflet midline 34 with the attachment curve. Thus, for example, the commissure is at zero percent and the intersection of the midline 34 with the attachment curve is at one-hundred percent. Half way along the attachment curve between those two points is at fifty percent.

Curve 42 illustrates the normalized distance along the surface of the leaflet between the triple point and each point on the concave attachment curve 38. Curve 44 illustrates the normalized distance along the surface of the leaflet between the triple point and each point on the convex attachment curve 40. On curve 44, the minimum distance point 46 occurs at approximately twenty percent and has a normalized value just less than 1.0. On curve 42, the minimum distance point 48 occurs at approximately thirty percent and has a normalized value of less than 0.9. Thus, the minimum distance along the surface of the leaflet from the triple point to the attachment curve is different for attachment curve 38 than it is for attachment curve 40. Further, the minimum distance point is in a different location for attachment curve 38 than it is for attachment curve 40.

Because of this difference in the minimum distance and the position of the minimum distance point, the point of maximum loaded stress along the attachment curve is different for attachment curves 38 and 40, as illustrated in Fig. 10. The chart in Fig. 10 has a vertical axis representing normalized stress with the normalization factor being the maximum stress shown on the Figure. The horizontal axis is the same as the horizontal axis in Fig. 9.

Curve 50 illustrates the loaded stress along concave attachment curve 38. Curve 52 illustrates the loaded stress along convex attachment curve 40. Curves 50 and 52 were produced by performing a finite element analysis of the respective geometries of the convex and concave leaflet designs.

As can be seen from Fig. 10, the point of maximum loaded stress 54 on convex attachment curve 52 occurs between the twenty- and thirty-degree points and experiences a normalized stress of approximately 0.90. The point of maximum loaded stress 56 on concave attachment curve 50 occurs between the thirty- and forty-degree points and experiences a normalized stress of 1.0. This demonstrates that the point of maximum loaded stress can be moved and the amount of stress that point experiences can be changed by changing the geometry of the attachment curve through modification of the valve body geometry.

The amount of stress experienced by the point of maximum loaded stress can be further modified by changing the geometry of the valve body 12 to increase the distance from the leaflet s point of maximum displacement or triple point to regions 58, 60 of points in the vicinity of points of maximum loaded stress, 62, 64, on the leaflet s attachment curve, as shown in Fig. 11. This change may cause the point of maximum loaded stress to change location, which may make it necessary to change the geometry of the attachment curve to reposition the point of maximum loaded stress once again. If necessary, the design of the attachment curve and the distance from the point of maximum displacement or the triple point can be iteratively revised until design criteria are met.

Further, the maximum loaded stress can be spread over the regions 58 and 60 of the leaflet by designing the attachment curve so that the regions 58 and 60 are equally distant from the point of maximum displacement or the triple point. The result would be a region of points experiencing maximum loaded stress rather than a single point, further reducing the likelihood of leaflet failure at the single point.

If the geometry of valve body 12 is held constant, the point of maximum loaded stress can be moved by changing the geometry of the leaflet. For example, if the leaflet has a cylindrical shape, changing the radius of curvature of the leaflet will move the point of maximum loaded stress, as illustrated in Figures 12, 13 and 14. If cylindrical leaflet 66 intersects valve body 12, the attachment curve will have the shape of curve 68, for example, and the leaflet will have triple point 70 and bottom point 72. If cylindrical leaflet 74, which has different radius than leaflet 66 but shares triple point 70 and bottom point 72, intersects valve body 12, the attachment curve will

have the shape of curve 76, for example. Consequently, attachment curve 76 is different from attachment curve 68 and the point of maximum loaded stress on leaflet 66 is in a different location than the point of maximum loaded stress on leaflet 74.

Another way to move the point of maximum loaded stress by changing the geometry of the leaflet is to change the shape of the leaflet, as illustrated in Figs. 15, 16, 17, 18 and 19. If leaflet 78, which has the shape of a conic section and a triple point 80, a bottom point 82 and commissures 84 and 86, intersects valve body 12, the attachment curve will have the shape of curve 88, for example. If leaflet 90, which has a cylindrical shape and shares triple point 80, bottom point 82 and commissures 84 and 86, intersects valve body 12, the attachment curve will have the shape of curve 92, for example. If leaflet 94, which has the shape of a conic section different from that of leaflet 78 and which shares triple point 80, bottom point 82 and commissures 84 and 86, intersects valve body 12, the attachment curve will have the shape of curve 96, for example. The point of maximum loaded stress is different for each of these leaflets 78, 90 and 94 because their attachment curves have different geometries.

In the preferred embodiment, the leaflet geometry is circularly cylindrical and the valve body geometry is convex of cylindrical resulting in the attachment curve 40 illustrated in Figs. 7 and 8.

In an alternative embodiment, an example of which is illustrated in Fig. 20, the valve body 98 has a different shape at the elevation of the attachment curve than its shape at its base. In Fig. 20, leaflet 100 is coupled to valve body 98 along attachment curve 102. The base of the valve body 100 has a circular shape 104. The attachment curve 102 is shaped so that its projection onto the plane containing circle 104 is not a circle. Thus, the attachment curve 102 can be shaped to locate the point of maximum loaded stress to meet design requirements while not affecting other design parameters, such as the shape of the valve body 12 where the sewing ring 20 is coupled to it.

The foregoing describes preferred embodiments of the invention and is given by way of example only. For example, the invention is not limited to heart valve technology but is equally applicable to any valve with flexible leaflet occluders. The invention is not limited to any of the specific features described herein, but includes all variations thereof within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A valve comprising

a valve body (12) having an attachment curve (16) having a first end and a second end;

a valve leaflet (14) coupled to the valve body (12) along the attachment curve (16), said valve leaflet (14) having a surface and a free edge (18) having a center point (30);

characterized by

the attachment curve (16) being configured so that a shortest distance measured along the surface of the valve leaflet (14) between the center point (30) of the free edge (18) and the attachment curve (16) is smaller than either of the distances measured along the surface of the valve leaflet (14) between the center point (30) of the free edge (18) and the first end and the second end of the attachment curve (16).

2. The valve of claim 1 further comprising a leaflet support (24) coupled to said leaflet (14) and said valve body (12), said valve body (12) further comprising a longitudinal axis (26), characterized by at least a portion of said leaflet support (24) having a non-cylindrical shape relative to the longitudinal axis (26).

3. The valve of claim 1 further characterized by the shape of said leaflet support (24) being configured to locate a point of maximum loaded stress on the leaflet away from a location of stress risers on the leaflet.

4. The valve of claim 1 further characterized by the coupling between the valve body (12) and the leaflet (14) being an integral attachment.

5. The valve of claim 1 further comprising a second valve leaflet and

a commissure (32) between the leaflet (14) and the second leaflet;

characterized by the commissure (32) being the location of stress risers.

6. The valve of claim 1 further characterized by the attachment curve (16) being configured to have a region of substantially uniform maximum loaded stress along the attachment curve (16).

7. The valve of claim 6 further characterized by the region of substantially uniform maximum loaded stress comprising a range of points along the attachment curve (16) being substantially a same distance, measured along the surface of the leaflet (14), from the center point (30) of the free edge (18), said region being closer to the center point (30), measured along the surface of the leaflet (14), than any point along the attachment curve (16) that is not among the points in the region of maximum loaded stress.

8. A method of making a valve comprising

providing a valve body (12) having a longitudinal axis (26);

providing a valve leaflet (14) having a surface and a free edge (18) having a center point (30),

characterized by providing an attachment curve (16) on said valve body (12), said attachment curve having a first end and a second end, and coupling said valve leaflet (14) to said attachment curve (16) such that the shortest distance along the surface of the leaflet (14) from the center (30) of the free edge (18) to a point along the attachment curve (16) is less than the distance along the surface of the leaflet from the center (30) of the free edge (18) to the first end of the attachment curve (16).

9. The method of claim 8 further characterized by coupling said valve leaflet (14) to said attachment curve (16) such that the point of maximum loaded stress on the leaflet is away from a location of stress risers, said attachment curve (16) having an expanded radius relative to the longitudinal axis (26) of said valve body (12).

10. A valve comprising

a valve body (12) having an attachment curve (16) comprising a first end and a second end;

a valve leaflet (14) coupled to the valve body (12) along the attachment curve (16), said valve leaflet being movable between an open position and a closed loaded position and having a point of maximum displacement between the open and closed loaded positions, characterized by the shortest distance along a surface of the valve leaflet from the point of maximum displacement to a point along the attachment curve being less than the distance along the surface of the valve leaflet from the point of maximum displacement to an end of the attachment curve.

11. The valve of claim 10 further characterized by the point of maximum displacement being a center of a free edge of the valve leaflet (14).

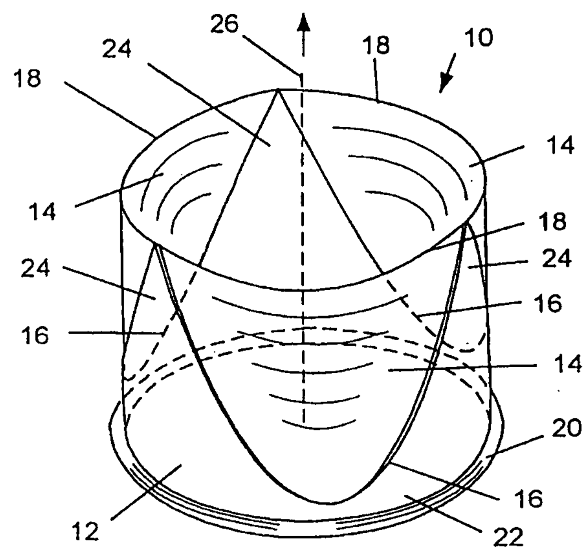

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Fig. 1

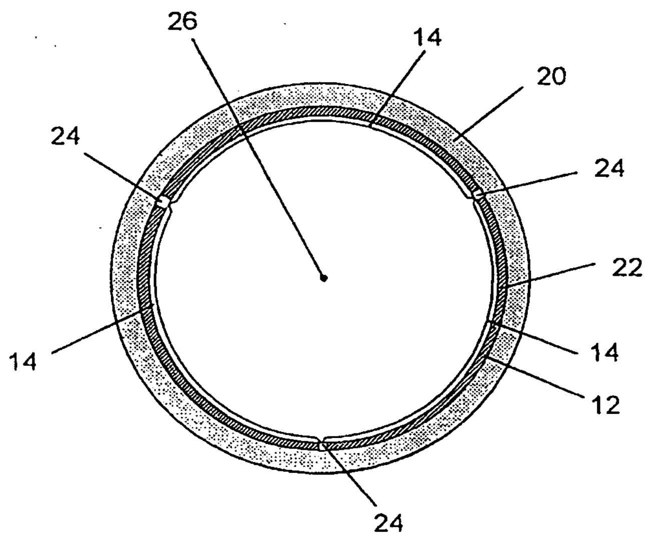
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Fig. 2

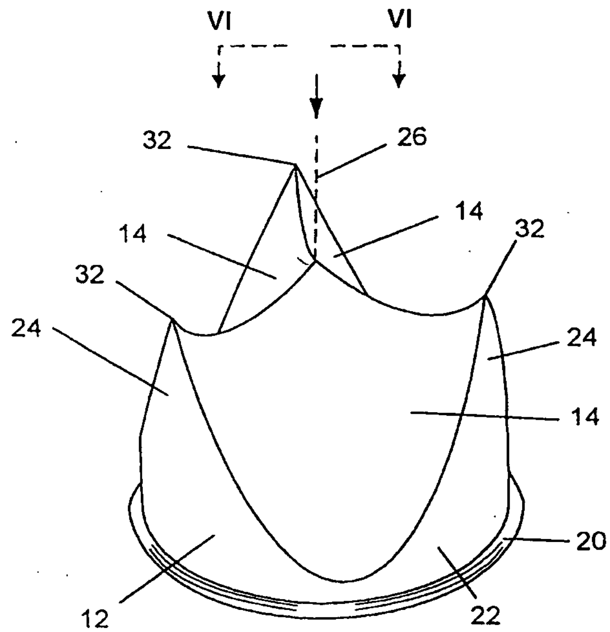
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Fig. 3

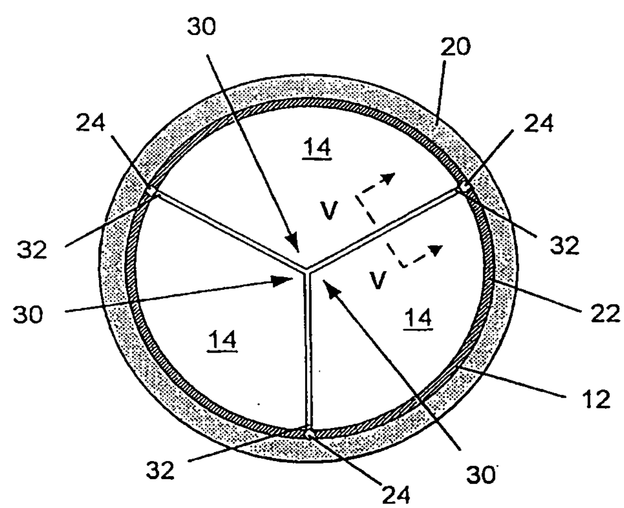
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Fig. 4

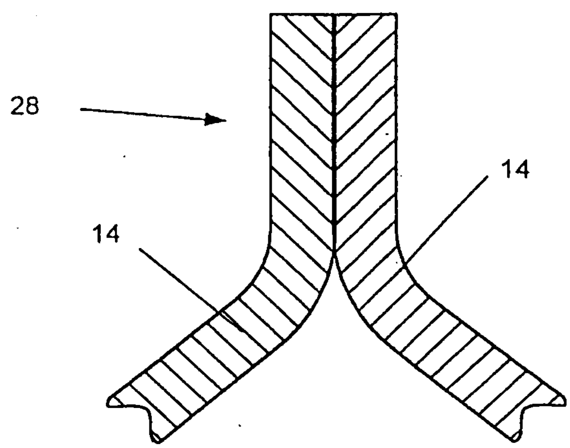


Fig. 5

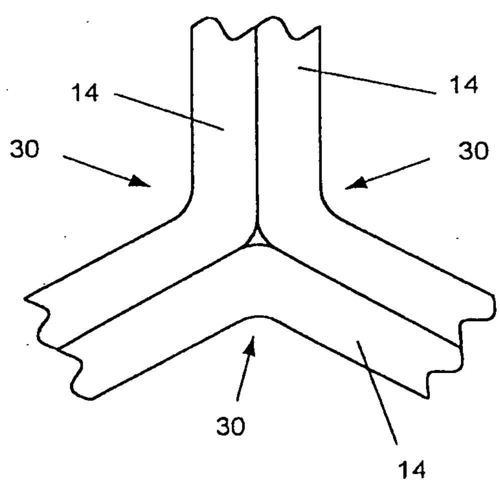
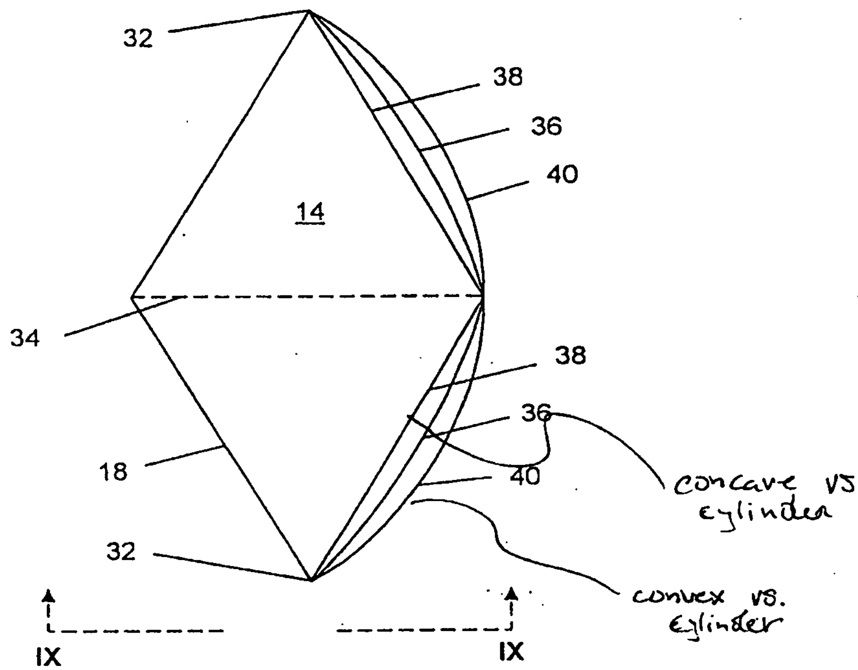


Fig. 6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cylinder
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Fig. 7

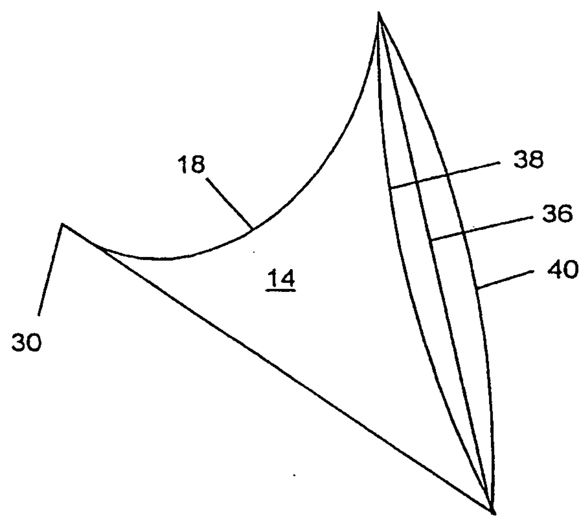
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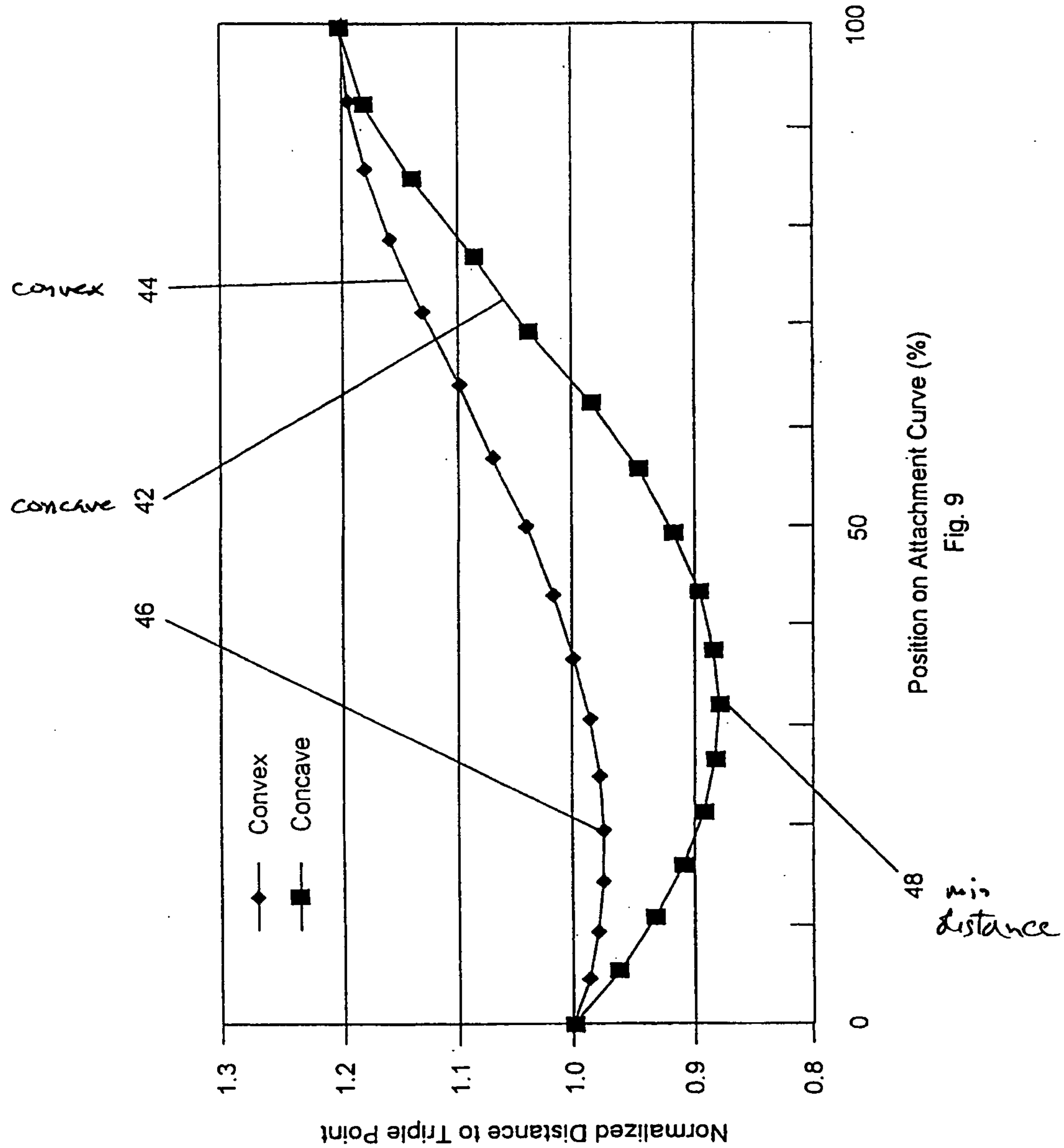
Fig. 8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concave 42
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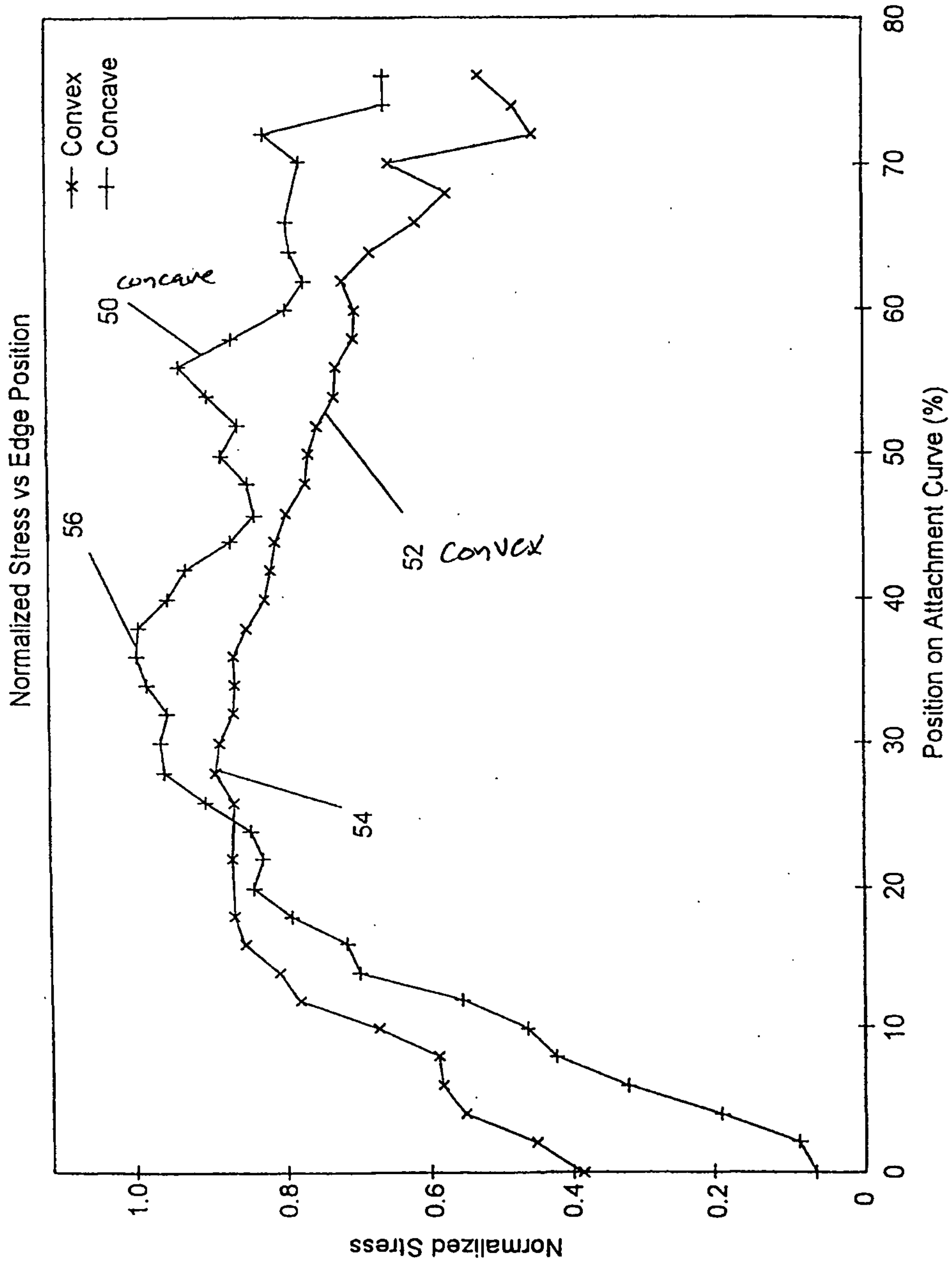
Fig. 9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1.0
0
10
20
30
40
50
60
70
80
Position on Attachment Curve (%)

Fig. 10

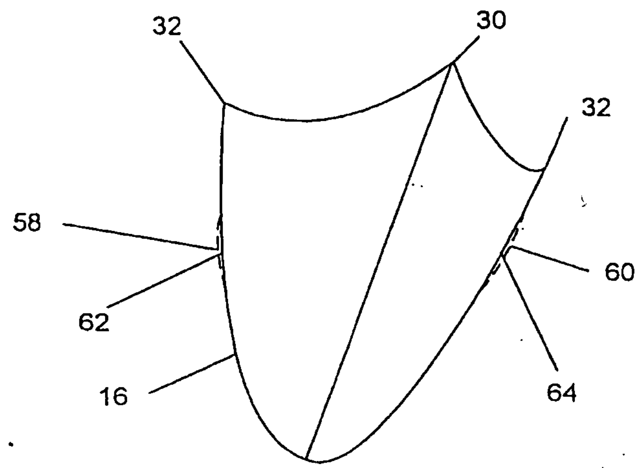

Fig. 11

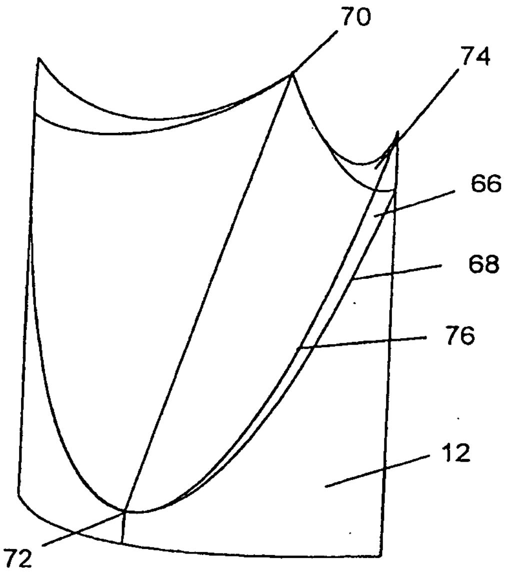

Fig. 12

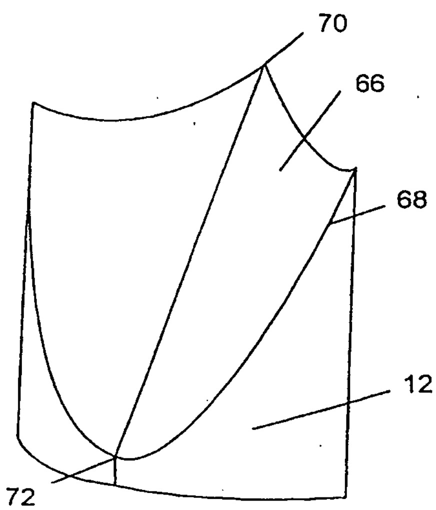

Fig. 13

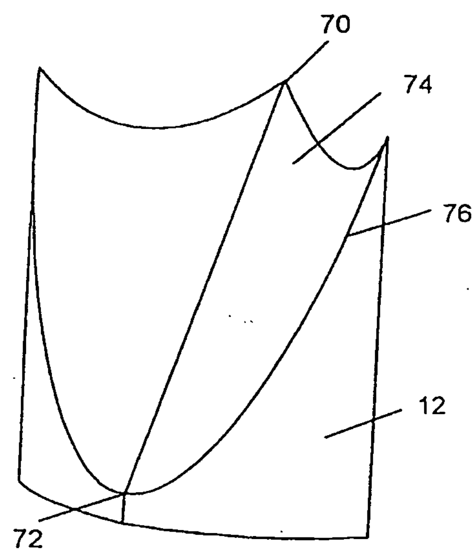

Fig. 14

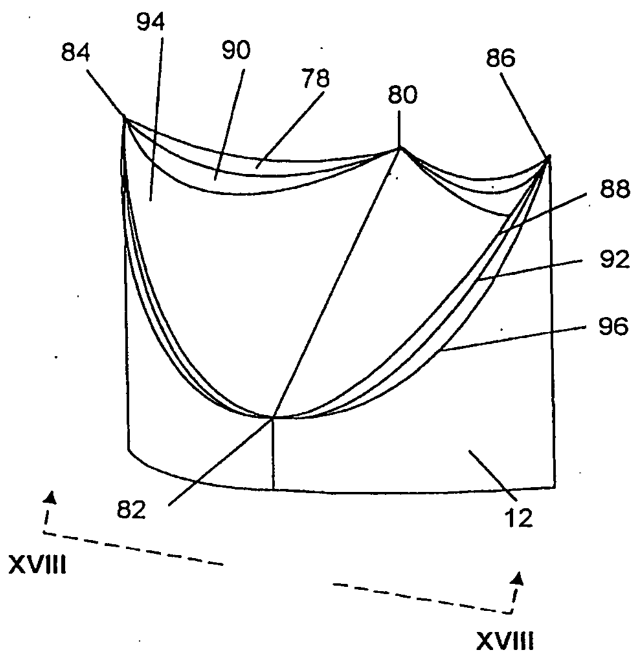

Fig. 15

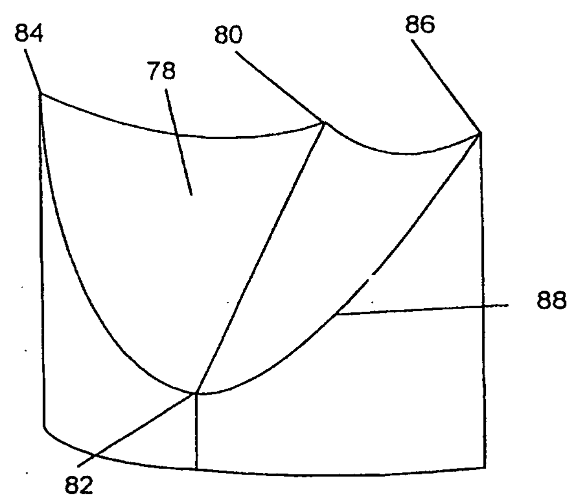

Fig. 16

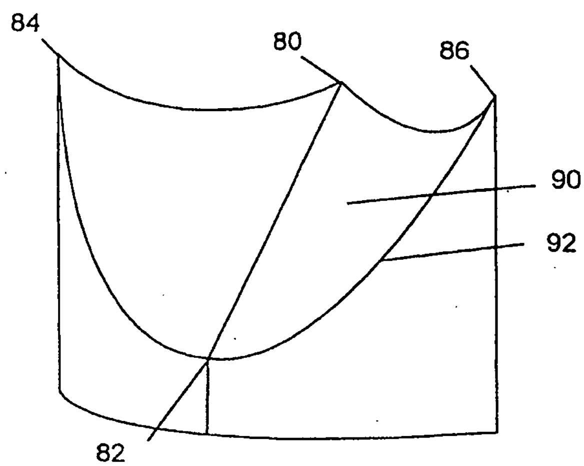

Fig. 17

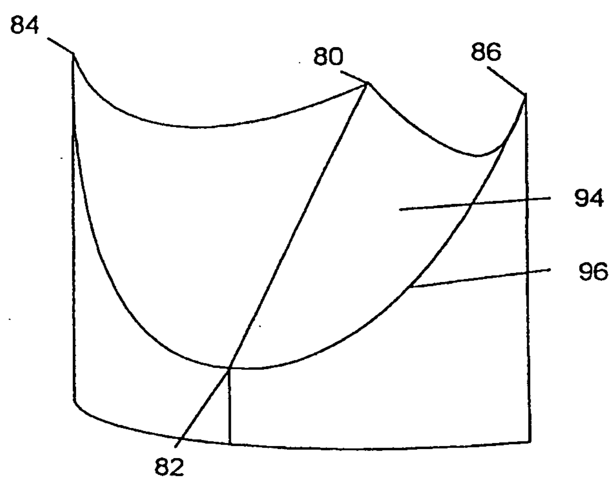

Fig. 18

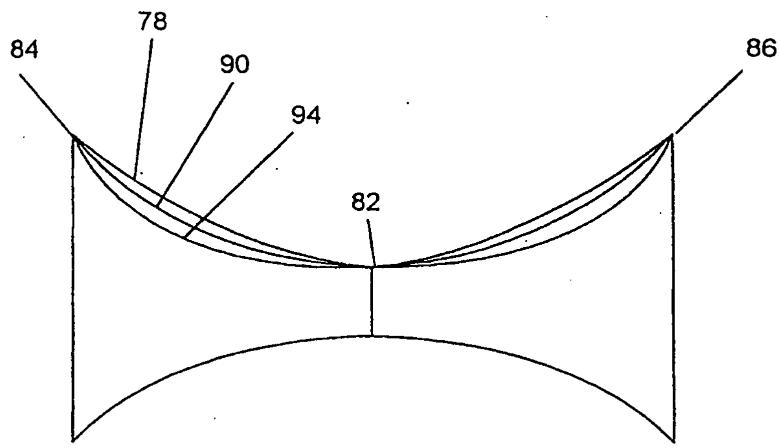

Fig. 19

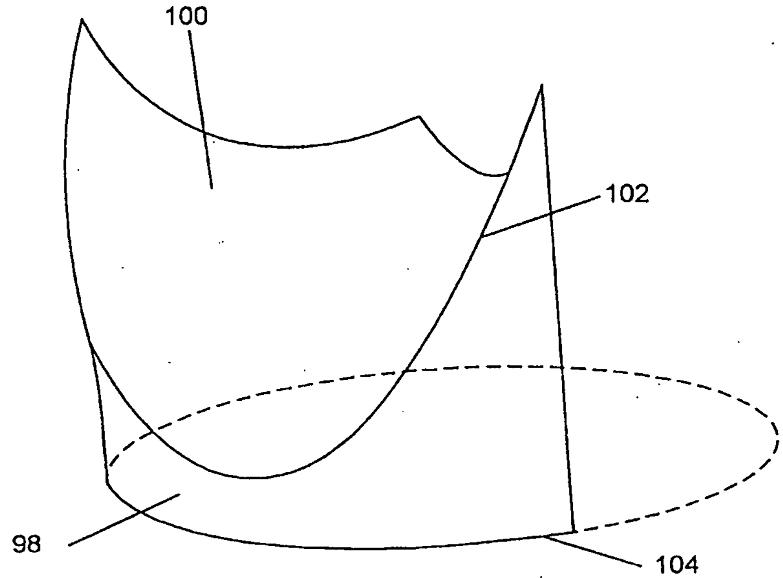

Fig. 20